

Part I Overview Information

Department of Health and Human Services

Participating Organizations

National Institutes of Health (NIH), (<http://www.nih.gov/>)

Components of Participating Organizations

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), (<http://www.niams.nih.gov>)

Title: Centers of Research Translation

Announcement Type

New

Request for Applications (RFA) Number: RFA-AR-05-005

Catalog of Federal Domestic Assistance Number(s)

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Key Dates

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Letters of Intent Receipt Date(s): September 26, 2005

Application Receipt Dates(s): October 25, 2005

Peer Review Date(s): January-February 2006

Council Review Date(s): May 2006

Earliest Anticipated Start Date: July 1, 2006

Additional Information to Be Available Date (Url Activation Date): April 11, 2005:

<http://www.niams.nih.gov/rtac/funding/grants/cortwww.htm>.

Expiration Date: October 26, 2005

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for Centers of Research Translation (CORTs) (P50). It is expected that a CORT will be translational in nature, directed at elucidating the relevance of basic research to human disease in an area within the NIAMS mission. Two major features of the CORT program include: 1) the overarching aim of disease-specific research translation, and 2) the inclusion of resources and an administrative structure to facilitate research translation.
- The funding of four new grants is anticipated.
- Up to \$6 million in total costs (Direct costs plus Facilities and Administrative costs) may be awarded in support of this solicitation.

- Eligible organizations will generally be an organizational unit within a university -affiliated medical center and may include:
 - For-profit organizations
 - Non-profit organizations
 - Public or private institutions, such as universities, colleges, hospitals, and laboratories
 - Units of State government
 - Units of local government
 - Eligible agencies of the Federal government
 - Domestic Institutions
 - Foreign Institutions are not eligible to apply
 - A principal investigator may submit only one application.
- Eligible principal investigators include individuals with the skills, knowledge, and resources necessary to carry out the proposed research and to work with their institutions to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.
- General application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format.
- Application instructions and materials specific to the P50 grant mechanism are available at http://www.niams.nih.gov/rtac/funding/grants/centers_programs.htm#P50.
- For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.
- Telecommunications for the hearing impaired: TTY 301-451-0088

Table of Contents

[Part I Overview Information](#)

[Part II Full Text of Announcement](#)

[Section I. Funding Opportunity Description](#)

1. Research Objectives

[Section II. Award Information](#)

1. Mechanism(s) of Support
2. Funds Available

[Section III. Eligibility Information](#)

1. Eligible Applicants
 - A. Eligible Institutions
 - B. Eligible Individuals
2. Cost Sharing or Matching
3. Other - Special Eligibility Criteria

[Section IV. Application and Submission Information](#)

1. Address to Request Application Information
2. Content and Form of Application Submission
3. Submission Dates and Times
 - A. Receipt and Review and Anticipated Start Dates
 1. Letter of Intent
 - B. Sending an Application to the NIH
 - C. Application Processing
4. Intergovernmental Review

5. Funding Restrictions
6. Other Submission Requirements

[Section V. Application Review Information](#)

1. Criteria
2. Review and Selection Process
 - A. Additional Review Criteria
 - B. Additional Review Considerations
 - C. Sharing Research Data
 - D. Sharing Research Resources
3. Anticipated Announcement and Award Dates

[Section VI. Award Administration Information](#)

1. Award Notices
2. Administrative and National Policy Requirements
3. Reporting

[Section VII. Agency Contact\(s\)](#)

1. Scientific/Research Contact(s)
2. Peer Review Contact(s)
3. Financial/ Grants Management Contact(s)

[Section VIII. Other Information - Required Federal Citations](#)

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

- The primary objective of the CORT Program is to foster research that is translational in nature, directed at elucidating the relevance of basic research to human disease in an area within the NIAMS mission. Two major features of the CORT program include: 1) the overarching aim of disease-specific research translation, and 2) the inclusion of resources and an administrative structure to facilitate research translation.

Translational research is defined as applied and clinical scientific research that is directed towards testing the validity and limits of applicability of knowledge derived from basic science and engineering to the understanding of human diseases and health. It could be research involving living human subjects (i.e., clinical) but it might also be non-clinical involving the study of human genes, tissues, specimens, or cells. Thus, although it is directed towards generation of knowledge about humans, it could be non-clinical or clinical research. It could be knowledge useful to persons (individuals, families, populations) affected by or at risk for specific diseases.

- Overall, the CORT should encompass a multidisciplinary approach to a disease-targeted theme. Individual projects must relate to the overall theme. For purposes of the projects within a CORT, translation is NOT to be interpreted as requiring one project to depend on another. Rather, the outcomes of each project should inform the others. That is, the outcomes of a clinical research project would not be dependent on the outcome of a basic research project.
- A CORT must be focused on one of the diseases in the NIAMS mission. The focus cannot be generic, e.g.: autoimmune diseases, musculoskeletal disorders, or skin diseases. The

diseases within the NIAMS mission may be found at:

<http://www.niams.nih.gov/rtac/funding/faq.htm>.

- CORT principal investigators must be drawn from different research disciplines, and may be based in different departments, divisions and/or institutions. There must be an existing research base supporting the projects.
- There must be a minimum of three highly meritorious projects with at least one basic and one clinical project. Overall the CORT concept is dual, embracing both the translation of new scientific information to clinical application and the application of clinical findings to new research.

NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.

- Each CORT will have an advisory group that includes scientific members who can facilitate the translational process and lay members who can bring the patient perspective about the disease to the group and guide the translational direction. The advisory group will have a dual role. One role will be to provide scientific and lay oversight of the ongoing progress of the CORT projects. A second role will be to review and recommend pilot and feasibility project applications for submission to NIAMS.
- The minimal structure for a CORT will be:
 - At least three highly meritorious translational research projects with at least one basic and one clinical project;
 - An Administrative Core with an advisory group that includes scientific and lay members.
 - The CORT Director should also be the principal investigator of one of the research projects.
- One or more research cores may also be proposed if they are critical to at least two of the projects and will enhance and facilitate the research.
- Pilot and feasibility projects to develop new directions in the translational theme may be submitted to NIAMS as administrative supplements. Up to three pilot and feasibility projects may be submitted once per year during the second and third year of CORT funding. The scientific review of these individual pilot and feasibility project applications will be directed by the CORT advisory group. NIAMS will make the final decision on acceptance of these projects based on programmatic priorities and funds available. Projects approved by NIAMS are eligible to receive up to \$50,000 per year in direct costs. Pilot and feasibility projects are optional.

See [Section VIII, Other Information - Required Federal Citations](#), for policies related to this announcement.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the P50 award mechanism(s). As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses the just-in-time budget concepts. It also uses the non-modular budget format described in the PHS 398 application instructions (see <http://grants.nih.gov/grants/funding/phs398/phs398.html>). A detailed categorical budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" is to be submitted with the application.

2. Funds Available

- The NIAMS expects to award up to \$6 million dollars in total costs in FY 2006 through this announcement;
- Up to 4 awards are anticipated;
- Direct costs of up to \$1,000,000 per year may be requested;
- July 1, 2006, is the earliest possible award date;
- The project period will be up to 5 years.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases intends to commit up to \$6 million dollars in FY 2006 to fund up to 4 new grants in response to this RFA. An applicant may request a project period of up to 5 years and a budget for direct costs up to \$1,000,000 dollars per year.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation, see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-004.html>.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State government
- Units of local government
- Eligible agencies of the Federal government
- Domestic Institutions
- Foreign Institutions are not eligible to apply.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from

underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

2. Cost Sharing or Matching

There are no requirements for cost sharing, matching, or cost participation for eligibility.

3. Other-Special Eligibility Criteria

Any institution or consortium with an active program of excellence in both basic and clinical biomedical research in arthritis, or musculoskeletal or skin diseases may qualify for support through a CORT.

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/us/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

Additional application instructions and materials specific to the P50 grant mechanism are available at <http://www.niams.nih.gov/rtac/funding/grants/cortwww.htm>. These guidelines are intended to assist the applicant in assembling an application in a manner to facilitate an optimal review.

3. Submission Dates and Times

Applications must be received on or before the receipt date described below ([Section IV.3.A](#)). Submission times N/A.

3.A. Receipt, Review and Anticipated Start Dates

Letter of Intent Receipt Date: September 26, 2005
Application Receipt Date(s): October 25, 2005
Peer Review Date: January-February 2006
Council Review Date: May 2006
Earliest Anticipated Start Date: July 1, 2006

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document.

The letter of intent should be sent to:

Charisee Lamar, Ph.D., M.P.H.
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Extramural Program
Centers Program Director
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892
Telephone: (301) 594-2463
FAX: (301)-480-4543
Email: lamarc@mail.nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Charisee Lamar, Ph.D., M.P.H.
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Extramural Program
Centers Program Director
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892
Telephone: (301) 594-2463
FAX: (301)-480-4543
Email: lamarc@mail.nih.gov

Using the RFA Label: The RFA label available in the PHS 398 application instructions must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face

page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/labels.pdf>. Personal deliveries of applications are no longer permitted.

3.C. Application Processing

Applications must be **received on or before the application receipt date(s)** described above ([Section IV.3.A.](#)). If an application is received after that date, it will be returned to the applicant without review. Upon receipt, applications will be evaluated for completeness by the CSR and responsiveness by the NIAMS. Incomplete and non-responsive applications will not be reviewed.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm> (see also [Section VI.3. Reporting](#)).

Pre-Award Costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing continuation award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing continuation award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part6.htm.

6. Other Submission Requirements

Additional application instructions and materials specific to the P50 grant mechanism are available at <http://www.niams.nih.gov/rtac/funding/grants/cortwww.htm>.

Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research must include a plan for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy (http://grants.nih.gov/grants/policy/data_sharing).

The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part7.htm#_Toc54600131). Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

Unique research resources may be generated in a core of the proposed CORT. If this is anticipated, include a resource sharing plan in the core proposal.

Section V. Application Review Information

1. Criteria

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance to program priorities

Additional review criteria are described below:

2. Review and Selection Process

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIAMS. Incomplete and/or non-responsive applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NIAMS in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Approach. Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation. Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigators. Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria:

Review Criteria for CORT Leadership:

Do the Director and Associate Director have the leadership and research qualifications to lead a Center? Does the leadership team (Director, Associate Director, and advisory group) have the

collective expertise to assure focused development and implementation of high quality and meaningful translational research?

Is the management program proposed appropriate for soliciting, reviewing and prioritizing pilot and feasibility project applications for submission to NIAMS?

Review Criteria for Administrative Core:

Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the CORT Director and Associate Director for the effective management of the CORT ? Is either the Center Director or Associate Director a clinical investigator who will be responsible for the translation of basic research to clinical research?

Is the management proposed appropriate for scientific administration as well as fiscal administration, procurement, property and personnel management, planning, budgeting, etc.?

Is there a plan for the establishment and maintenance of internal communication and cooperation among the CORT investigators? Are there plans for effective use of the CORT advisory group?

Review Criteria for Research Base:

Is there a substantial productive and funded research base? Is the research base sufficiently broad to foster new multidisciplinary translational research?

Review Criteria for Institutional Environment and Resources:

Is there evidence of a supportive institutional environment for the proposed CORT? Will the CORT add an important multidisciplinary element to the institutional environment? Does the proposed CORT utilize available resources well?

Review Criteria for Research Cores:

Will the core have utility to at least two of the CORT projects?

Is the quality of services high? Are there procedures for quality control? Is the core cost effective?

Do the services offered best fit within a core structure? If this is an add on to a preexisting core, what is the benefit to the CORT over direct purchase of services from the existing core?

Are the personnel appropriate?

Are the facilities and equipment adequate? Is there institutional commitment to the core?

Review Criteria for Projects:

Significance

Does this study clearly address the theme of the CORT? Will the outcomes inform the other projects in the CORT? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive the field?

Approach

Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation

Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator

Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Collaboration

Does the project advance the theme of the CORT and inform the other projects?

Review of the Overall Application:

After the review of the individual components of the application, an overall priority score will be assigned to the application. This score will reflect not only the individual quality of the projects, cores, and administration, but also how the proposed CORT will bring together all these elements in a workable unit. The overall score may be higher or lower than the "average" of the descriptors based on the assessment of whether the "whole is greater than the sum of its parts":

The scientific excellence of the Center's research base as well as the relevance and interrelation of these separately-funded research projects to the goals of the Center and the likelihood for meaningful collaboration among Center investigators. The application must convey how the proposed Center will enhance significantly the established research base of the host institution.

The overall environment for a Center. This includes the institutional commitment to the program, including lines of accountability regarding management of the Center, and the institution's partnership with the Center, and the institutional commitment to individuals responsible for conducting essential Center functions. This also includes the academic environment and resources in which the activities will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools to enhance a multidisciplinary approach.

The overall priority score assigned to the application will also reflect the policies regarding (a) the inclusion of women, minorities and children in study populations and (b) the protection of human subjects from research risks.

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2.C. Sharing Research Data

Data Sharing Plan: The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy.
http://grants.nih.gov/grants/policy/data_sharing.

2.D. Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#availofrr and http://ott.od.nih.gov/newpages/rtguide_final.html). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing plans with the awardee before recommending funding of an application. The final version of the data and resource sharing plans negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590). See [Section VI.3. Reporting](#).

3. Anticipated Announcement and Award Dates

Not applicable

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and

Conditions of NIH Grant Awards, Subpart A: General
(http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm).

A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant organization. The NGA signed by the grants management officer is the authorizing document.

Once all administrative and programmatic issues have been resolved, the Notice of Grant Award will be generated via e-mail notification from the awarding component, NIAMS, to the grantee business official (designated in item 14 on the application Face Page). If a grantee is not e-mail enabled, a hard copy of the Notice of Grant Award will be mailed to the business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Also [Section IV.5. Funding Restrictions](#).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

3. Reporting

Annual progress reports, submitted as part of the noncompeting continuation application, are due two months before the anniversary date of the award. These reports are used by the National Institute of Arthritis and Musculoskeletal and Skin Diseases to review the Center and its progress. They serve to verify in detail the achievement of the objectives outlined in the initial application and award and are an important source of material for program staff in preparing reports, planning programs, and communicating scientific accomplishments.

The application for continuation of a PHS Grant, PHS Form 2590, is used to file the annual report. In addition, an overall progress report containing the following information should be included:

- A summary (equivalent to no more than four single spaced typewritten pages) of the goals and significant activities of the CORT. This summary should be prepared for a general audience. Honors and/or promotions of professional personnel should be mentioned.
- A discussion of the effectiveness of the CORT grant in furthering the goals of the CORT program. This should include a summary of the specific accomplishments that can be attributed to the CORT grant, e.g., new research funding, changes in curricula, or organizational improvements within the institution and in the community.
- An itemization of collaborative efforts the CORT established.
- A list of publications relevant to CORT funding should be provided.
- A discussion of problems that impede accomplishment of the stated goals in the administration of the CORT grant and plans to overcome them.
- The administrative component report should include a list of administrative meetings held, evaluations from advisory groups, speakers or symposia sponsored. These may be included as appendix material.
- A table listing the assurance dates for IACUC, IRB and certifications education for the protection of human research participants for key personnel for all CORT-funded projects is optional, but will assist the timely processing of the award. (See Exhibit VI). The notice describing the educational requirement for the protection of human subject participants may be found at <http://www.niams.nih.gov/rtac/funding/grants/notice/notod00-039.htm>.

- A detailed summary of each CORT funded component (including the Administrative Core) and project, including the title, principal investigator and key personnel, their percent effort, proposed budgets, description, progress, and evaluation. This progress report should include all CORT-supported projects. It is especially important that the significance and ultimate utility of each project be discussed in the summary description and that this discussion be in terms understandable to an informed nonscientist.
- A budget page for the coming year for each component and project funded by the CORT.
- The timely review of the application will be facilitated by the inclusion of a composite budget for the entire CORT as illustrated in Exhibit IV.
- Other information that, from year to year, may be requested by the NIAMS staff.
- The expanded progress report is in addition to, and does not replace, other management reports required by PHS policy.

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (<http://grants.nih.gov/grants/funding/2590/2590.htm>) and financial statements as required in the NIH Grants Policy Statement.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Charisee Lamar, Ph.D., M.P.H.
 National Institute of Arthritis and Musculoskeletal and Skin Diseases
 Extramural Program
 Centers Program Director
 6701 Democracy Boulevard, Suite 800, MSC 4872
 Bethesda, MD 20892
 Telephone: (301) 594-2463
 FAX: (301)-480-4543
 Email: lamarc@mail.nih.gov

2. Peer Review Contacts:

Yan Wang, Ph.D.
 National Institute of Arthritis and Musculoskeletal and Skin Diseases
 Extramural Program
 Acting Chief, Review Branch
 6701 Democracy Boulevard, Suite 800, MSC 4872
 Bethesda, MD 20892-4872
 Telephone: (301) 594-4952
 FAX: (301) 402-2406
 Email: wangy1@mail.nih.gov

3. Financial or Grants Management Contacts:

Melinda Nelson
 National Institute of Arthritis and Musculoskeletal and Skin Diseases
 Extramural Program
 Grants Management Officer

6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nelson1@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

Sharing Research Data:

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

Required Education on the Protection of Human Subject Participants:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

Human Embryonic Stem Cells (hESC):

Criteria for federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov/>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

Public Access to Research Data through the Freedom of Information Act:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: <http://www.lrp.nih.gov/>.
